



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR - 6 1998 2582 98 MAR 17 P1:41

Ms. Deborah Shur Trinker
Director of Regulatory Affairs
and Corporate Counsel
Rexall Sundown, Inc.
851 Broken Sound Parkway NW
Boca Raton, Florida 33487-3693

Dear Ms. Trinker:

This is in response to your letter of February 17, 1998 to the Food and Drug Administration (FDA) pursuant to 21 USC 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act)). Your submission states that Rexall Sundown, Inc. is making, among other claims, the following claims for the products:

Horse Chestnut:

“For leg vein health, circulation and swelling”

Garlic:

“...helps lower serum cholesterol”

21 USC 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases and conditions. These claims do not meet the requirements of 21 USC 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 USC 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Florida District Office, Office of Compliance, HFR-SE240

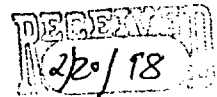
cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456:rjm:3/4/98:docname:57268.adv:disc26



851 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188
Email Address: RSRegDpt@aol.com

February 17, 1998



Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Rexall Sundown, Inc. located at 851 Broken Sound Parkway, N.W., Boca Raton, Florida 33487, within the next 30 days will be marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

Horse Chestnut: [It] is a traditional remedy used for centuries to help maintain vascular integrity and to enhance circulation in the legs. Horse Chestnut trees grow abundantly in Europe and the United States. Sundown's Horse Chestnut is standardized to 55mg Escin, and also provides additional beneficial components such as Flavones and Tennins for leg vein health. For leg vein health, circulation and swelling.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed

Sincerely,

A handwritten signature in cursive script that reads "Deborah Shur Trinker".

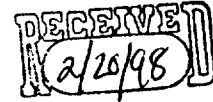
Deborah Shur Trinker
Director of Regulatory Affairs
and Corporate Counsel

Enclosure



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February 17, 1998



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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
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Garlic: For thousands of years the Chinese have valued garlic for its exceptional healing properties. Research studies indicate that the use of garlic helps lower serum cholesterol and provides important cardiovascular, immune system and digestive health benefits. For healthy cholesterol levels.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed

Sincerely,

A handwritten signature in cursive script, appearing to read "Deborah Shur Trinker".

Deborah Shur Trinker
Director of Regulatory Affairs
and Corporate Counsel

Enclosure

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